IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
Civil 14-2094 ES

MYLAN PHARMACEUTICALS,

PLAINTIFF

V.

ORAL OPINION

CELGENE CORPORATION,

DEFENDANT.

NEWARK, NEW JERSEY
DECEMBER 22,2014

B E F O R E: HONORABLE ESTHER SALAS,
UNITED STATES DISTRICT JUDGE

Pursuant to 753 Title 28 United States Code, the following transcript is certified to be an accurate record as taken stenographically in the above-entitled proceedings.

S/ LYNNE JOHNSON

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Official Court Reporter

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THE COURT: Before the Court is Defendant Celgene Corporation's motion to dismiss the Complaint filed by Mylan Pharmaceuticals, Inc. (D.E. No. 17). The Court has considered the briefs submitted by the parties and the Federal Trade Commission, (D.E. Nos. 17-1, 24, 26-3, and 31), as well as the arguments presented by counsel at oral argument on December 9, 2014. For the reasons below, the Court GRANTS *without prejudice* in part and denies in part Celgene's motion to dismiss.

II. LEGAL STANDARD

To survive a motion to dismiss, a complaint must only allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. V. Twombly*, 550 U.S. 544, 570 (2007). A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashscroft v. Iqbal*, 556 U.S. 662, 678 (2009). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.*

"When reviewing a motion to dismiss, '[a]ll allegations in the complaint must be accepted as true, and the plaintiff must be given the benefit of every favorable inference to be drawn therefrom.'" *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011) (quoting *Kulwicki v. Dawson*, 969

F.2d 1454, 1462 (3d Cir. 1992)). But the court is not required to accept as true "legal conclusions," and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678.

The Third Circuit has expressly cautioned that "it is inappropriate to apply *Twombly*'s plausibility standard with extra bite in antitrust and other complex cases." *West Penn Allegheny Health Sys. Inc. V. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010).

III. FACTS

Celgene is a branded drug company that manufactures and distributes two life-saving but dangerous drugs: Thalidomide (Thalomid) and lenalidomide (Revlimid). (Compl. ¶¶ 2-3).

Thalomid was approved in 1998 to treat lesions associated with leprosy. (*Id.* ¶ 59). It was later indicated for co-use with another drug to treat multiple myeloma. (*Id.* ¶ 3). In connection with the FDA approval of Thalomid, Celgene adopted the System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.), a program for distributing the drug in accordance with strict safety protocols. (*Id.* ¶ 4). In 2007, when Congress gave the FDA statutory authority to condition the approval of drug application on acceptable safety protocols, called Risk Evaluation and Mitigation

Strategies (REMS), S.T.E.P.S. was deemed an approved REMS program (D.E. No. 17-1 ("Moving Br.") At 7-8). Celgene has several patents covering Thalomid, the last of which expires in 2023. (*Id.* At 9).

Remlivid was approved in 2005 for the treatment of a subset of multiple myeloma, myelodysplastic syndrome, and mantle cell lymphoma patients. As with Thalomid, Celgene distributes Remlivid through a REMS program. Celgene's patents on Remlivid extend through 2027. (*Id.* At 11). Mylan, a generic drug company, alleges that Celgene has maintained an unlawful monopoly over Thalomid and Revlimid by preventing lower-priced generic competition from entering the market. (Compl. ¶ 2). Specifically, Mylan alleges that Celgene "used REMS as a pretext to prevent Mylan from acquiring the necessary samples to conduct bioequivalence studies." (*Id.* ¶ 7). The FDA requires any generic drug application to include bioequivalence studies comparing the generic product with the branded product. (*Id.* ¶ 8).

a. Thalomid

Mylan began efforts to develop a generic version of Thalomid in September 2003. (Compl. ¶ 13). It originally tried to obtain samples through wholesale distribution channels, but was unable to do so because of the S.T.E.P.S. program. (*Id.* ¶ 75).

In October 2004, Mylan sent a letter to Celgene

through a third party requesting to purchase Thalomid samples. Seven months later, it sent a second request. Celgene responded in June 2005, confirming that Thalomid is unavailable through wholesale distribution and stating that it was against policy to deal with intermediaries in the sale of Thalomid. (*Id.* ¶¶ 75-76).

Mylan reached out to Celgene directly in September 2005. (*Id.* ¶ 77). One month later, Celgene wrote back to explain that it needed additional time to respond given the requirement that Thalomid is distributed exclusively through S.T.E.P.S. (*Id.* ¶ 77-78). In December 2005, Celgene responded that it would need the FDA's agreement to allow samples to be distributed outside of S.T.E.P.S. and recommended that Mylan contact the FDA. (*Id.* ¶ 79).

Mylan contacted the FDA in January 2006, requesting that the FDA provide Celgene with written authorization for it to provide Thalomid samples and providing the protocols for its 3 planned studies. (*Id.* ¶¶ 80-82). The FDA responded to request that Mylan provide either an investigational new drug ("IND") application or a more detailed study protocol. (*Id.* ¶ 83). Mylan submitted the requested study protocols in May 2007. (*Id.* ¶ 84).

In September 2007, the FDA responded that Mylan's Thalomid protocols were "acceptable," and included additional recommendations that Mylan would need to follow in conducting

its studies. (Id. ¶ 86). Mylan informed Celgene of the FDA's letter in November 2007 and reiterated its request for samples. It followed up again in December. (*Id.* ¶¶ 87-89). In January 2008, Celgene responded and asserted that it could still not provide samples due to "concerns about distributing Thalomid outside of the S.T.E.P.S. program [that] are independent of FDA's regulatory oversight." It instead requested that Mylan produce to Celgene ten categories of information relating to Mylan's planned use of the samples, history of FDA compliance, product liability insurance, etc. (*Id.* ¶¶ 90-99).

Mylan responded in February, agreeing to deliver the information on a confidential basis and enclosing a confidentiality agreement. Celgene responded with proposed edits to the agreement in April and June 2008. The agreement was executed in June 2008, and Mylan sent its materials to Celgene. (*Id.* ¶¶ 102-07). In addition, Mylan stated that it would agree to indemnify Celgene for any liability resulting from Mylan's studies. (*Id.* At 108).

Celgene responded with a draft indemnification agreement in August 2008, and Mylan sent a responsive letter in October 2008 expressing concerns about the agreement's overbreadth. (*Id.* ¶¶ 113-14). The parties eventually reached agreement on the terms of indemnification in April 2009. (*Id.* ¶¶ 120).

In October 2008, while the negotiations over the indemnification agreement were ongoing, Celgene sent Mylan a second request for information. Mylan responded with additional information in April 2009. Celgene again sought more materials about Mylan's insurance coverage in June 2009. (*Id.* ¶¶ 118-20).

Finally, after attempting to engage with Celgene for almost five years to procure samples, Mylan "recognized that further engagement with Celgene would be fruitless." (*Id.* ¶ 128).

b. Revlimid

Mylan alleges that Celgene followed a "nearly identical path of delay" for Revlimid, and that it worked to obtain samples from August 2009 to May 2012. (*Id.* ¶¶ 130, 134).

Mylan submitted its safety protocols for Revlimid bioequivalence studies to the FDA in August 2012. The FDA deemed them "acceptable" in October 2012 but requested additional information. (*Id.* ¶ 135-36). In addition, the FDA told Mylan that it would be willing to inform Celgene that the FDA had received sufficient assurance regarding any planned testing. (*Id.* ¶ 137). In November 2012, Mylan provided additional information requested by the FDA and gave the FDA permission to notify Celgene once Mylan's protocols were approved. In February, the FDA requested additional

information and identified more recommendations, and Mylan responded again in May 2013. In July 2013, the FDA informed Mylan that its protocols were adequate and that it would notify Celgene to request that Celgene provide Mylan with samples. (*Id.* ¶¶ 138-142).

Mylan wrote to Celgene in May 2013 to inform Celgene that the FDA letter was forthcoming and to request the samples. In response, Celgene advised Mylan that it needed to wait until it received notice from the FDA. In addition, as it had for Thalomid, Celgene requested additional information from Mylan and indicated that it would require an indemnification agreement. (*Id.* ¶¶ 143-147).

In January 2014, Mylan submitted to the FDA (at its request) a formal Disclosure Authorization to the FDA allowing it to contact Celgene and share with it the fact that the FDA had received a request from Mylan for assistance in obtaining samples. In March 2014, following final endorsement of its safety profiles, Mylan again sent a letter to Celgene notifying that it would not engage in back-and-forth correspondence as it did with Thalomid and asking Celgene to provide samples by March 14, 2014. (*Id.* ¶¶ 149-50). It also sent an executed indemnification agreement. (*Id.* ¶ 151).

Celgene responded on March 20, 2014 that it required eight additional categories of information. It also

did not sign the agreement, indicating that it would consider the terms after receiving the additional information. (*Id.* ¶¶ 152-56).

III. DISCUSSION

a. § 2 CLAIMS

Celgene urges the Court to dismiss Mylan's claims under § 2 of the Sherman Act. A plaintiff alleging a § 2 violation must plead: (1) monopolization; and (2) "the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Verizon Communs., Inc. V. Law Offices of Curtis v. Trinko,* LLP, 540 U.S. 398, 407 (2004) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). Here, the parties dispute element (2), also known as requirement of "anticompetitive" or "exclusionary" conduct. Celgene argues that its conduct is not exclusionary as a matter of law because Section 2 does not impose an affirmative duty to deal with competitors except under limited circumstances, which it argues are inapplicable here. (Moving Br. At 14). Mylan argues that that Celgene's conduct falls within the scope of cases where a duty to deal applies. (D.E. No. 24 ("Opp. Br.") at 14). The Court finds that Mylan has pled facts that may plausibly give rise to a duty to deal, and therefore denies Celgene's motion to dismiss Mylan's § 2 claims.

In general, there is no affirmative duty to deal with competitors. *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). However, this right is not unqualified, and an affirmative duty to deal may arise under limited circumstances. *See generally Trinko*; *Aspen Skiing Co. V. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985); *Otter Tail Power Co. V. United States*, 410 U.S. 336 (1973). The parties primarily dispute the scope of the exception, and the factors that must be present for an affirmative duty to arise—particularly, whether a prior course of dealing between the parties is required.

Celgene argues that there is an affirmative duty to deal with competitors only when (1) there is a prior course of dealing between the parties; and (2) the alleged monopolist irrationally forsook short-term profits for long-term anticompetitive gain—in other words, its actions made "no economic sense." (Moving Br. At 14). Mylan responds that it only needs to plead the second factor, and that there is no requirement of a "prior course of dealing" between the parties. (Opp. Br. At 20).

The parties (and the Court's) consideration of the scope of the exception to the "no duty to deal" rule begins with *Aspen Skiing*. In *Aspen Skiing*, the Supreme Court held that a defendant violated § 2 when it terminated a long-standing, profitable business relationship in which the

parties offered joint ski passes to both parties' ski mountains. *Aspen Skiing*, 472 U.S. at 587-95. The Supreme Court wrote that the "most significant" evidence supporting § 2 liability was the suggestion that the defendant's conduct was not "justified by any normal business purpose." *Id.* At 608. To the contrary, the defendant "elected to forgo [] short-run benefits because it was more interested in reducing competition in the Aspen market over the long run." *Id.* *The Supreme Court revisited Aspen Skiing* nearly 20 years later in *Trinko*. In *Trinko*, the Supreme Court held that Verizon's failure under the Telecommunications Act of 1996 to facilitate market entry by competitors did not state a § 2 claim. It held that "*Aspen Skiing* is at or near the outer boundary of § 2 liability," *Trinko*, 540 U.S. at 409, and proceeded to distinguish *Aspen Skiing* on a series of facts. Significantly, the Supreme Court explained that, in *Aspen Skiing*, the "unilateral termination of a voluntary (*and thus presumably profitable*) course of dealing suggested a willingness to forsake short-term profits to achieve an anticompetitive end." *Id.* (Emphasis in original). In *Trinko*, on the other hand, "the complaint does not allege that Verizon ever engaged in a voluntary course of dealing with its rivals," and therefore "its prior conduct sheds no light upon whether its lapses from the legally compelled dealing were anticompetitive." *Id.* Thus, the Supreme Court reasoned

that "prior course of dealing" was relevant to the § 2 inquiry insofar as it served as a proxy for the larger inquiry of whether the defendant's conduct was anticompetitive.

Trinko also distinguished itself from *Aspen Skiing* on grounds that, in *Aspen Skiing*, the defendant refused to sell a product to its competitor at retail price even though it had sold it at that price to others. *Id.* This fact was further indicative of anticompetitive conduct, and missing from the record in *Trinko*. *Id.* There can be not dispute that the question of whether a defendant sold its product at retail -- like the issue of "prior course of dealing" -- is relevant to determining whether Section § 2 liability applies. But it appears that the *Trinko* Court considered these facts not for their independent significance, but rather for what they *suggest*: A willingness to engage in irrational, anticompetitive conduct.

The Third Circuit cases to consider the scope of the "no duty to deal" do not appear to adopt a strict requirement that a party must plead "prior course of dealing" for its claims to proceed. Celgene has not cited a case in the Third Circuit where a motion to dismiss was granted for failure to allege a prior course of dealing. To the contrary, the cases in our Circuit that have considered the scope of the affirmative duty to deal suggest that a "prior

course of dealing" is relevant but not dispositive in determining whether such a duty applies.

In *BroadCom Corp. V. Qualcomm Incorp.*, 501 F.3d 297 (3d Cir. 2007), the Third Circuit determined that the limited exception to the "no duty to deal" rule applied even though the plaintiff did not plead a prior course of dealing. (Footnote 1) *Id.* At 316. The Third Circuit explained that the Supreme Court "created an exception to this [no duty to deal] rule by holding that the decision of a defendant who possessed monopoly power to terminate a voluntary agreement with a small rival *evidenced* the defendant's willingness to forego short-run profits for anticompetitive purposes." *Id.* At 316 (citing *Aspen Skiing*, 472 U.S. at 610-611) (emphasis added). Though the plaintiff in *BroadCom* did not allege a prior course of dealing, the Third Circuit found that there was other anticompetitive conduct that distinguished the facts from *Trinko* and aligned it more closely with *Aspen Skiing*.(Footnote 2) *Id.*

For example, the defendant, QualComm, marketed the allegedly withheld technology for inclusion in an industry-wide standard and voluntarily agreed to license it on certain terms. *Id.* Thus, under *BroadCom*, a prior course of dealing is relevant as "evidence[] of the defendant's willingness to forego short-term profits for anticompetitive purposes," but where other such evidence exists, the failure

to plead prior dealing is not a death knell. *Id.*

Likewise, the district court cases in our Circuit do not appear to require pleading a prior course of dealing. Perhaps most significantly, two courts in the District of New Jersey have denied motions to dismiss on facts similar to those currently before the Court. *Actelion Pharm. Ltd. V. Apotex, Inc.*, No. 12-5743, D.E. No. 90 (D.N.J. Oct. 21, 2013) (denying motion for judgment on the pleadings "for reasons stated during oral argument"); *Lannett Co., Inc. V. Celgene Corp.*, No. 8-3920, D.E. No. 42 (E.D. Pa. Mar. 30, 2011) (denying motion to dismiss without comment). (Footnote 3)

In *Actelion*, as here, a branded pharmaceutical manufacturer refused to sell samples of a product distributed pursuant to a REMS program to its generic competitor. Also as here, the defendant argued that the plaintiff's claims should be dismissed for failing to allege a prior course of dealing between the parties. Judge Hillman ruled during oral argument that the § 2 claims could proceed, noting that "if the defendants can prove that the plaintiffs are motivated not so much by safety concerns but instead motivated by the desire to use the REMS or REMS equivalent, to use exclusive distribution agreements and to use a otherwise legitimate refusal to deal together to maintain and extend a monopoly, then they may very well make out a Section 2 claim." *Id. at 117. Judge Hillman also noted that facts other than prior*

course of dealing—such as the "refusal to sell at retail" and attempt to control prices—were evidence of anticompetitive conduct in Aspen Skiing and, accordingly, determinative of its outcome. *Id.* at 13-14. Accordingly, the fact that the plaintiff in *Actelion* did not plead a prior course of dealing did not automatically preclude a § 2 claim because it pled other facts to demonstrate that the defendant's actions were motivated only by long-term anticompetitive gain.

Most recently, the Eastern District of Pennsylvania had the opportunity to address the scope of an affirmative duty to deal in *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, No. 13-2445, D.E. No. 97 (E.D. Pa. Dec. 3, 2014). There, the court held that the exception described in *Aspen Skiing* did not apply because there was no prior course of dealing between the parties. However, *Suboxone* is distinguishable from this case because it did not consider whether facts other than prior dealing demonstrated the defendant's willingness to forego short-term profits for anticompetitive gain. In fact, the *Suboxone* court recognized that "*Lannett* and *Actelion* are distinguishable because the elements to assure safe use in those cases prevented the generics from obtaining the brand-name pharmaceutical to conduct bio equivalency testing during the REMS process." *Id.* At 28. The *Suboxone* court would have been aware that the plaintiffs in *Lannett* and *Actelion*

did not plead a prior course of dealing, and therefore recognizes that other facts in those cases (and this one) may give rise to § 2 liability.

To be sure, there are cases that weigh "prior course of dealing" more heavily. For example, the Second Circuit has dismissed § 2 claims for failing to allege a prior course of dealing between the parties. *In Re Elevator Antitrust Litig.*, 502 F.3d 47, 53 (2007). In reaching its decision, the Second Circuit relied on the Supreme Court's reasoning that the "unilateral termination of a voluntary (*and thus presumably profitable*) course of dealing suggested a willingness to forsake short-term profits to achieve an anticompetitive end." *Id.* (Quoting *Trinko*, 540 U.S. at 409) (emphasis in original). Thus, even though *In Re Elevator* dismissed claims for failing to allege prior dealing, its focus was still on the willingness to forsake short-term profits for an anticompetitive end. It does not address whether other factors could also indicate such a willingness.

Indeed, the Supreme Court has "never held that termination of a preexisting course of dealing is a necessary element of an antitrust claim," *Helicopter Transport Servs., Inc. V. Erickson Air-Crane, Inc.*, No. 7-3077, 2008 WL 151833, at *9 (D. Or. Jan. 14, 2008), and there remains valid Supreme Court law imposing an affirmative duty to deal when no prior

course of dealing was alleged. *Otter Tail Power Co. V. United States*, 410 U.S. 366 (1973). There, the defendant was "in the business of providing a service to certain customers (power transmission over its network), and refused to provide the same service to certain other customers." *Trinko*, 540 U.S. at 410 (citing *Otter Tail*, 410 U.S. at 371, 377-78). In this way, the facts in *Otter Tail* align with the facts before this Court—there is no prior course of dealing between the parties themselves, but there was prior business between Celgene and other generic companies and research organizations. The Supreme Court's finding of an affirmative duty in *Otter Tail* (as well as its discussion of that case in *Trinko* without overruling it) lends further support to Mylan's argument that a prior course of dealing is not required.

Here, Mylan essentially admits that it has not plead a prior course of dealing between the parties. Nevertheless, the Court finds that Mylan's Complaint pleads facts that, if true, may give rise to a plausible § 2 claim. To start, Mylan has pled that there is no legitimate business reason for Celgene's actions, which it argues are solely motivated by its goal to obtain long-term anticompetitive gain. (*See, e.g.*, Compl. ¶¶ 158-170).

It has further pled that Celgene has sold samples of Thalomid and Revlimid at retail and provided it to

research organizations, but refuses to sell to Mylan because of its anticompetitive goals. *Id.* Though Celgene vigorously disputes these allegations, the Court finds that Mylan's pleadings are sufficient to allow the case to proceed to discovery, especially because the Court's inquiry at this stage does not require any probability of success. The Court is convinced that Mylan has pled its § 2 claims with sufficient detail to justify moving the case beyond the pleadings to the next stage of litigation.

b. SECTION § 1 CLAIMS

Mylan's § 1 claim alleges that Celgene devised an anticompetitive scheme to prevent Mylan and others from filing ANDAs for generic versions of Thalomid and Revlimid, and that Celgene entered into unlawful agreements with wholesale distributors and pharmacies to unduly restrain trade.

A plaintiff asserting a Section 1 claim must assert four elements: (1) a concerted action by defendants (2) that produced anti-competitive effects within the relevant product and geographic markets; (3) that the concerted actions were illegal; and (4) that plaintiff was injured as a proximate result of the concerted action. *Howard Hess Dental Labs. Inc. V. Dentsply Intern., Inc.*, 602 F.3d 237, 253 (3d Cir. 2010). Here, Celgene challenges that Mylan has adequately pled elements (1) and (4)--concerted action and proximate

causation. The Court finds that Mylan has not adequately pled a concerted action between Celgene and its alleged coconspirators and therefore grants Celgene's motion to dismiss Mylan's § 1 claims. Because the Court dismisses these claims based on failure to plead concerted action, it does not need to reach whether proximate causation is present.

"The essence of a Section 1 claim is the existence of an agreement." *Gordon v. Lewiston Hosp.*, 423 F.3d 184, 207 (3d Cir. 2005) (citing *Mathews v. Lancaster Gen'l Hosp.*, 87 F.3d 624, 639 (3d Cir. 1996). Unilateral action does not support Section 1 liability. Rather, there must be a "unity of purpose or a common design and understanding or meeting of the minds in an unlawful arrangement." *Siegel Transfer, Inc. V. Carrier Express*, Inc., 54 F.3d 1125, 1131 (3d Cir. 1995) (quoting *Copperweld Corp. V. Independent Tube Corp.*, 467 U.S. 752, 771 (1984)). To establish concerted action, there must be a "relationship between pressure from one conspirator and the anticompetitive decision of another conspirator." *Gordon*, 423 F.3d at 207 (citing *Big Apple BMW v. BMW of North America*, 974 F.2d 1358, 1363 (3d Cir. 1992).

Celgene argues that Mylan has merely alleged the existence of agreements with agents and servicing entities that have no competitive interest in the market, no interest in harming Mylan, and no knowledge of Mylan's anticompetitive

objective. (Br. at 25-27). Celgene argues that these allegations cannot give rise to a § 1 claim. (*Id.* At 26). It adds that, to meet the § 1 pleading requirements, Mylan must allege that independent actors agreed to a common plan or scheme. (D.E. No. 31 ("Rep. Br.") at 17).(Footnote 4)

Mylan responds that Celgene's purported pleading burden is too high. It states that it has discharged its pleading burden by "directly alleging the existence of restrictive distribution contracts between Celgene and downstream entities," (Opp. Br. At 29), and that "unity of purpose is not required" in pleading a § 1 claim. (December 9, 2014 Hearing Transcript ("Tr.") at 69).

Mylan's argument that it does not need to plead any unity of purpose relies on *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171 (3d Cir. 1992). In *Fineman*, the Third Circuit reversed a directed verdict on the Plaintiff's § 1 claim, which the district court granted after "determining that 'under no set of circumstances based on this record could the jury reasonably find that Stern shared Armstrong's purpose of eliminating TINS from competition in the video magazine market.'" *Id.* At 212. The Third Circuit found the district court's approach "misplaced as it renders section 1 claims unavailable to private litigants suffering antitrust injury as a result of concerted action in a vertical matrix." Instead of requiring that the coconspirators share a *motive*,

the Third Circuit held that "the emphasis is on the participant's '*commitment to [the] scheme* [which is] designed to achieve an unlawful purpose." *Id.* (Quoting *Edward J. Sweeny*, 637 F.2d at 111) (emphasis in original). It further held that a "rational factfinder could infer commitment to the scheme among coconspirators "despite differing motives." *Id.*

The Third Circuit in *Fineman* thus discharged the requirement that a plaintiff must plead an identical motive among co-conspirators perpetuating a restraint on trade. This is logical given that, in an alleged vertical conspiracy, the interests of the coconspirators are different by nature—in fact, the Third Circuit noted that it "cannot conceive of a situation in which vertically aligned co-conspirators seeking to destroy a competitor of only one could satisfy this requirement [of identical motive]." *Id.* At 213.

Yet the Court in *Fineman* did *not* eliminate the requirement that a plaintiff alleging a § 1 violation must plead an agreement to a common scheme or design—regardless of each coconspirator's motive for agreeing to it. In fact, Third Circuit in *Fineman* reiterated the key factors for § 1 liability articulated by it earlier in *Harold Friedman v. Thorofare Markets, Inc.*, 587 F.2d 127, 143 (3d Cir. 1978). There, the Third Circuit held that "knowledge of the 15 defendant's purpose to restrain trade is an important factor"

and "at least two members of the combination stood to benefit by the restraint of trade . . . Thus, in a sense, two members of the combination shared a common purpose insofar as they both benefited from the restraint of trade." *Id.* In *Fineman*, the Third Circuit found that both of these factors were present—the alleged conspirators had knowledge of the anticompetitive goal and stood to benefit from it, giving rise to a plausible § 1 violation. *Fineman*, 980 F.3d at 214. *Fineman* may fairly be read to hold plaintiff does not need to plead that § 1 coconspirators share a common motive, but it does not support Mylan's argument that a § 1 plaintiff does not need to plead any agreement to a common plan or scheme whatsoever. (FOOTNOTE 5)

The Third Circuit reaffirmed the § 1 pleading standard in *Siegel Transfer, Inc. V. Carrier Express, Inc.*, 54 F.3d 1125 (3d Cir. 1995), in which the Circuit held that there was no § 1 violation because the alleged coconspirators were "[c]ontractually obligated to manage Carrier Express affairs" and represented a single enterprise." *Siegel Transfer, Inc. V. Carrier Express, Inc.*, 54 F.3d 1125, 1135 (3d Cir. 1995). As such, they were not capable of conspiracy. *Id.* Third Circuit reiterated that § 1 liability requires a "unity of purpose or a common design and understanding or meeting of the minds in an unlawful arrangement." *Id.* At 1131 (quoting *Copperweld Corp. V.*

Independent Tube Corp., 467 U.S. 752, 771 (1984)).

The most recent case that Mylan relies on, *West Penn*, also fails to support the sufficiency of its pleadings. Mylan cites *West Penn* for the proposition that "[i]f a complaint includes non-conclusory allegations of direct evidence of an agreement, a court need go no further on the question whether an agreement has been adequately pled." *West Penn*, 627 F.3d at 99. Yet Mylan ignores *West Penn*'s explicit definition of an "agreement," which is "a unity of purpose, a common design and understanding, a meeting of the minds, or a conscious commitment to a common scheme." *Id.* (Citing *Copperweld*, 467 U.S. at 771).

For example, in *West* Penn, the Plaintiff specifically alleged that the coconspirators ". . . Formed an agreement to protect one another from competition. Plaintiff asserts that UPMC agreed to use its power in the provider market to exclude Highmark's rivals from the Allegheny health insurance market, and that in exchange Highmark agreed to take steps to strengthen UPMC and to weaken its primary rival, West Penn." *Id.* At 100.

Thus, while a contract may be an "agreement" pursuant to § 1 if there is evidence that it represents a unity of purpose, meeting of the minds, or conscious commitment to a common scheme, Mylan has not pointed to any case holding that it is enough to simply plead that a

contract exists. In fact, the Third Circuit has held that there is no agreement under § 1 "when a party has simply entered into a permissible contract with the defendant or when the defendant has enforced a contractual right with another party." *Friedman, Inc. V. Kroger Co.*, 581 F.2d 1068, 1078 (3d Cir. 1978). Mylan appears to conflate evidence of a *contract* with evidence of an unlawful "agreement" to restrain trade under § 1.

Here, the Court finds that Mylan's Complaint fails to assert non-conclusory allegations of an unlawful agreement between Celgene and its distributors or competitors that would give rise to § 1 liability. In fact, the only paragraphs in the Complaint that Mylan points to as supporting its allegations of a common scheme are ¶¶ 261, 262, 274, and 275. (Tr. At 100). Those paragraphs allege that *Celgene* devised an anticompetitive scheme to prevent Mylan and others from entering the markets for Thalomid and Revlimid, and that *Celgene* entered into unlawful agreements to restrict distribution of those products. *Id.* Nowhere does Mylan plead that Celgene's distributors and pharmacists shared its purpose (even if they had different motives for doing so), or that they had a common anticompetitive goal. For example, there are no allegations that Celgene's pharmacists or distributors stood to benefit from the alleged anticompetitive scheme. *See Friedman*, 980

F. 2d at 1073. Nor does the Complaint allege that Celgene's distributors and pharmacists even had *knowledge* of Celgene's anticompetitive intent. *Id.* ("[K]knowledge of the defendant's purpose to restrain trade is an important factor.").

Finally, the Court further finds that Mylan has not even alleged that the purpose of the agreements between Celgene and its distributors was to unduly restrain commerce. Third Circuit has held that "contractual restraints fall within the prohibition of Section 1 only when their purpose and effect is found to have imposed an undue restraint on commerce." *Garhman v. Univ. Res. Holding, Inc.*, 641 F. Supp. 135, 1371 (D.N.J. 1986) (quoting *Sitkin Smelting v. FMC Corp.*, 575 F.2d 440, 447 (3d Cir. 1978). Thus, even if evidence of the contracts was sufficient to constitute an "agreement" under § 1, any restraint of trade appears to be collateral to the main purpose of the contracts, which is to distribute Revlimid and Thalomid pursuant to Celgene's REMS programs. Mylan has not alleged that the restraint of trade is a central purpose of the agreements between Mylan and its distributors and pharmacies. *See generally Friedman v. Kroger*, 581 F.2d at 1073; *Fineman*, 980 F.3d at 213.

Based on all of the above, the Complaint fails to "raise a reasonable expectation that discovery will reveal evidence of [an] illegal agreement," *Twombly*, 550 U.S. at 556, and Mylan's claims under § 1 of the Sherman Act must be

dismissed. The Court does not need to independently consider Celgene's "causation" element because it finds that Mylan failed to adequately plead concerted action.

c. Statute of Limitations

The parties agree that a four-year statute of limitations applies to Mylan's claims in this case. 15 U.S.C. § 15(b). The statute of limitations runs from when the plaintiff allegedly becomes injured by the defendant. The Court finds that this statute of limitations does not bar Mylan's claims as to Thalomid or its claims that rely on both Thalomid and Revlimid.

As an initial matter, the Court finds that Mylan adequately pled that Celgene refused samples within the limitations period: "Throughout this entire period, Celgene has engaged in a scheme (described at length below) to continuously prevent and/or stall all of Mylan's efforts to obtain samples of Thalomid and Revlimid." (Compl. ¶ 7). In addition, the Court finds that Mylan has pled that Celgene's continued refusal to deal throughout the limitations period constitutes an injurious act. *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1172 (3d Cir. 1993), held that "continuing and accumulating damage may result from intentional, concerted inaction. The purposeful nature of the inaction—here an ongoing refusal to sell or lease—obviously constitutes an injurious act, although

perhaps not an overt one in the commonly-understood sense." It further held that: "[A] conspiracy's refusal to deal, which began outside the limitations period, may be viewed as a continuing series of acts upon which successive causes of actions may accrue. Far from requiring that the plaintiff tie its damages to specific acts, the [Fifth Circuit] acknowledged that a continuing conspiracy may give rise to continually accruing rights of action, and the court simply required the plaintiff to support its allegation that the defendant had continued during the period in suit to refuse to deal." *Id.* At 1173 (internal quotations and citations omitted).

In *West Penn*, the Third Circuit reaffirmed that holding, and declined to time-bar claims on the grounds that the actions alleged to have occurred within the limitations period were "merely 'reaffirmations' of acts done or decisions made outside of the limitations period." *West Penn*, 627 F.2d at 106. There the Court held that the Defendant's argument would mean that "a plaintiff who suffers [damage from a continuing antitrust violation] is barred not only from proving violations and damages more than four years old, but is barred forever from complaining of [the continuation] of the unlawful conduct." *Id.* At 108 (internal quotations and citations omitted).

The Court finds this reasoning applicable here.

Celgene's continued refusal to deal constitutes an overtly injurious act that has occurred within the four-year limitations period. As a result, the Court will not bar Mylan's claims based on the applicable statute of limitations.

d. Relevant Market

Defining the "relevant market" for purposes of a monopoly is a necessary element of any antitrust claim, whether under § 1 or § 2. The scope of an antitrust product market is determined by the "reasonable interchangeability of use or the cross-elasticity of demand between the product itself and the substitutes for it." *Brown Shoe Co. V. United States*, 370 F.2d 20, 26 (3d Cir. 1978).

"In most cases, the proper market definition can only be determined after a factual inquiry into the commercial realities faced by consumers." *Queen City Pizza v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997). As such, courts typically decline to dismiss antitrust claims based on failure to plead the relevant market. That said, there is no *per se* rule prohibiting dismissal on this cases, and plaintiffs have the burden of defining the relevant market. "Cases in which dismissal on the pleadings is appropriate frequently involve either (1) failed attempts to limit a product market to a single brand, franchise, institution, or comparable entity that competes with

potential substitutes, or (2) failure even to attempt a plausible explanation as to why a market should be limited in a particular way." *Todd v. Exxon Corp.*, 275 F.3d 191, 200 (2d Cir. 2001).

Mylan has pled that the relevant market "in which to assess the anticompetitive effects of Celgene's conduct" concerning Thalomid and Revlimid is the market for each product plus bioequivalent generic versions. (Compl. ¶¶ 36, 46). Celgene argues that Mylan's single-market pleading is legally deficient, and that Mylan fails to explain why the market should be limited in this way. (Moving Br. At 30-36). Celgene is correct that courts are skeptical of single-product market definitions. *See, e.g., Am. Sales Co., Inc. V. Astrazeneca AB*, No. 10-6062, 2011 WL 1465786 (S.D.N.Y. Apr. 14, 2011) (rejecting market consisting solely of pharmaceutical product and its generic counterpart). Here, however, the Court declines to find Mylan's market definition legally insufficient on its face because there are factual questions that must be resolved. For example, it specifically alleged that the availability of other treatments for the indications that Thalomid and Revlimid are prescribed are not sufficient to prevent the anticompetitive effects of Celgene's conduct. (Compl. ¶¶ 37, 47).

Discovery is needed to determine, among other things, whether these allegations are true or whether, as

Celgene contends, other products serve as adequate market substitutes. (*See* Rep. Br. At 20-23).

Based on the above, the Court declines to dismiss Mylan's claims based on a failure to allege the relevant market.

e. No Injury

Injury is a necessary element of any antitrust claim. 15 U.S.C. §§ 15, 26. Celgene argues that Mylan has failed to allege an injury because it has not shown that it would be able to enter the market with generic versions of the products at issue. (Moving Br. At 36-37). The Court disagrees.

Though Celgene is correct that there are barriers to Mylan entering the market with generic versions of Thalomid and Revlimid, the bar is not absolute. For example, Mylan could argue that Celgene's patents are invalid or attempt to enter the market with a product that it alleges in noninfringing. In addition, Mylan is injured by Celgene's preventing it from entering the market immediately upon the expiration of its patents. In sum, the Court denies Celgene's motion to dismiss Mylan's claims for failure to assert an injury.

f. Conclusion

For the reasons above, the Court grants Celgene's motions to dismiss *without prejudice* for Mylan's claims under

§ 1 of the Sherman Act, counts 5-7, as well as the portions of Mylan's New Jersey Antitrust Act claims, counts 8 and 9, arising under Section 56:9-3. The Court denies Celgene's motion to dismiss with respect to the remaining counts.

SO ORDERED this 22nd day of December, 2014.

(Adjourned)

FOOTNOTES

FOOTNOTE 1. The Third Circuit acknowledged that though *BroadCom* was not a strict "refusal to deal case," if it "were to analyze it as such, [it] would find that the Complaint does not run afoul of established Supreme Court precedent" because the limited exception to the "no duty to deal" rule applied. *BroadCom*, 501 F.3d at 316.

FOOTNOTE 2. At oral argument, Counsel for Celgene argued that there was a "current relationship" between the parties in *BroadCom* because "Broadcom had already committed the license on FRAND terms." (Tr. At 34). However, it does not appear that Broadcom and Qualcomm ever reached a license agreement. Rather "Broadcom claims to have been preparing to enter the UMTS chipset market for several years . . . [And] Qualcomm allegedly demanded that Broadcom license Qualcomm's UMTS technology to non-FRAND terms. Broadcom refused, and commenced this action." *Broadcom*, 501 F.3d at 305. The Court does not agree that this constitutes a prior course of dealing between the parties as contemplated in *Aspen Skiing* and *Trinko*.

FOOTNOTE 3. Additionally, in *Only v. Ascent Media Grp., LLC*, No. 6-2123, 2006 WL 2865492 (D.N.J. Oct. 5, 2006), the Judge Hochberg noted in a footnote that there are three

"exceptional circumstances where a duty [to deal] may be recognized": First, the *Trinko* court "recognized that a 'concerted' refusal to deal may violate the Sherman Act under its prior decisions." Second, a "sudden refusal to deal on fair terms following a longstanding and mutually profitable business relationship may approach to boundary of Section Two liability." And third, there may be a limited exception when a defendant refuses to make available access to "essential facilities." *Id.* At *4 n.7. Therefore, at least one court in this Circuit has noted that a "concerted" refusal to deal may constitute an exception separate and apart from a prior course of dealing. *Id.*

FOOTNOTE 4. There is also an implication in Celgene's briefs that vertical agreements between manufacturers and distributors, such as those alleged here, are not suitable for § 1 claims. The Court notes that these types of agreements may give rise to such claims when adequately pled. *See, e.g., United States v. Ciba Geigy Corp.*, 508 F. Supp. 1118, 1146 (D.N.J. 1976) ("Although these contracts were reached in a vertical, supplier-purchaser, context, they, in fact, were designed to limit horizontal competition . . . . Such agreements are more pernicious antitrust violations than simple vertical restraints. . . .").

FOOTNOTE 5. In fact, the Third Circuit has

rejected arguments similar to Mylan's. In *Howard Hess Dental Labs. Inc. V. Dentsply Intern., Inc.*, 602 F.2d 237 (3d Cir. 2010), plaintiffs attempted to rely on *Fineman* to justify pleadings that "do not offer even a gossamer inference of any degree of coordination . . . ." The Third Circuit wrote that though *Fineman* held that vertically aligned co-conspirators need not share an identical motive, "nothing in that case excuses the Plaintiffs from alleging an agreement. . . ." *Dentsply*, 602 F.3d at 256 n.8.